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April 3, 2003

Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane Room 1061
HFA-305
Rockville, MD 20852

RE: Docket No. 02N-0278 RIN 0910-AC41, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (68 FR 5428, February 3, 2003)

Dear Sir or Madam:

The National Food Processors Association (NFPA) welcomes this opportunity to provide comments on the above referenced "Prior Notice" requirements of "The Bioterrorism Act" (The Act). NFPA is committed to the important goal of protecting the nation's food supply against intentional contamination and recognizes that the Food and Drug Administration (FDA) has been under significant pressure to meet key deadlines established by The Act. NFPA is striving to work closely with the FDA as regulations are being developed to respond appropriately to the security mandates of the Act without undue disruption to domestic commerce and international trade.

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NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA members import ingredients for further processing and export finished processed food products globally and will, consequently, be affected by this rulemakings. Since September 11, 2001, the food industry has taken aggressive steps towards protecting the nation's food supply. NFPA is providing the leadership for the Food Security Alliance, a coalition including over 130 organizations representing all levels of the food chain.

WASHINGTON, DC
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On August 30, 2003, NFPA submitted comments to the Food and Drug Administration (FDA) urging a seamless integration with existing and

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pending import notification requirements with the goal of minimizing or eliminating unnecessary, multiple or redundant notification. On March 5, 2003, NFPA submitted comments to the Office of Management and Budget (OMB) specifically related to the information collection aspects of the proposal. After careful evaluation of the FDA proposal, NFPA submits that the adverse impact on business operations and trade will be significant. Herein, we have identified those recommendations in the proposed rule that are burdensome, ineffective and go beyond the intent of the Act and provide alternative solutions that will be effective and reasonable.

General Comments

NFPA believes that the proposed prior notice requirements extend beyond that which is necessary to adequately respond to an incident of intentional contamination related to imported food and exceed the specific Congressional mandate of The Bioterrorism Act. FDA has failed to adequately take into consideration "the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported..." as recommended by Congress. Recognizing specific Congressional mandates regarding notice and timing, it is clear that Congress intended to provide FDA with the authority to exercise flexibility in order to minimize operational impacts and keep trade flowing.

NFPA is very concerned that substantial discussions with U.S. Customs have yielded, not an integrated system, but a duplicative system. Of particular concern is the impact on the large volume of cross border trade between the U.S. and Canada and the U.S. and Mexico, especially upon those operations close to the border dependent upon "just in time" inventories.

NFPA comments will demonstrate that FDA has grossly underestimated the economic burdens imposed by the proposed rules and the potential for trade disruption.

The Scope Expands Beyond the Congressional Mandate

Section 307 of the Act amends Section 801 of the Federal Food, Drug and Cosmetic Act and mandates the Food and Drug Administration (FDA) to issue regulations for the "purpose of enabling such article to be inspected at ports of entry." The statute requires a notice providing the "identity" of the article, the manufacturer, the shipper, the grower (if known in the specific time notice is required), the country of origin, the country of shipment and the anticipated port of entry for the article. NFPA believes that Congress intended FDA to receive sufficient information on imported products to be able to locate and identify specific articles of food for purposes of inspection before the articles are released into commerce.

In comments to OMB, NFPA stated that the proposed information requirements go beyond what is necessary to achieve the objective of the Act and identified specific data elements that should be eliminated. In the preamble to the proposal, FDA states that, in addition to providing information to allow FDA to "respond effectively to bioterrorism and other public health emergencies that might result from imported food," the proposed rule would be used to "facilitate product tracking;" to "assist FDA and other authorities in determining the source and cause of problems and in communicating with affected firms;" and to help "use foreign inspection resources more effectively." While FDA's intends to utilize this new information source for broader purposes, Congress was clear that an appropriate balance must be achieved between that information collection and the implications on trade including the operational practices of food businesses.

Product tracing for the purpose of recall is the responsibility of the food manufacturer. Information about consignees and customers is often deemed proprietary. Distribution information prior to entry and final consignees after entry is not relevant to satisfy the intent of the Congressional mandate, that is to identify and locate articles for inspection. In that regard, this information should not be mandated.

Recommendations – Information Collection

Eliminate unnecessary data fields. FDA has failed to demonstrate the practical utility of the detailed information solicitation under the proposal. The Bioterrorism Act provides FDA significant flexibility to minimize the information collection burden. For example, the Act indicates that the "submitter" must identify the manufacturer and shipper and grower, if known. Even FDA attempts "... to minimize confusion," under 1.278 (d), stating that the "carrier or the person who submitted the prior notice" must make arrangements for the movement of the food and the purchaser, owner, importer, or consignee is responsible for expenses. Therefore, NFPA concludes that for FDA purposes, there are two responsible parties (e.g the submitter and the party responsible for expenses). In addition, the law requires the manufacturer and shipper to be identified. Consequently, "in order to minimize confusion" FDA's data collection should specifically identify those two parties and those required by the Act and all additional mandatory fields should be eliminated. (See subsequent comments regarding responsible parties.)

Clarify Responsible Party. FDA is proposing to define "you," the party responsible for submitting the prior notice, as the "purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent... acting on behalf of the U.S. purchaser or importer." In many cases, the importer and the purchaser will not be the same. In order to identify one responsible entity for notification, NFPA recommends "you" be clarified to be the importer or his agent. Food products are often imported on behalf of an ultimate purchaser who may not have any of the information necessary for prior notice submission.

Exempt grower for processed food. The statute requires growers to be identified, if known. In most cases, growers will not be known for processed food products. In other cases, raw materials are purchased through cooperatives or brokerage markets where small amounts of commodities from many growers are combined. The importer may know none, some or as many as 30 of those small growers. Some of the information may be available on the grower, but not all the data indicated on the submission. The responsibility to provide this information is not clear (e.g. the form provides space for three growers.) Importers of processed food should be exempt from providing this information. FDA should clarify what will satisfy "if known." No imported food products should be detained for failure to provide complete information about the growers.

Define food; narrow the scope. The Statute mandates that prior notice shall apply to an article of food that is being imported or offered for import into the United States. The Act does not define "article of food," but FDA has used the definition of food in Section 201(f) of the Food, Drugs and Cosmetics Act (FD&C Act) which includes dietary supplements and ingredients, alcoholic beverages and "substances that migrate into food from food packaging materials." The use of this definition unnecessarily expands the scope to include packaging materials, not intended under the Act. The FD& C Act would also include components of food, but it is not always clear when a component becomes a food. For example, when citric acid is imported for a non-food use (e.g. detergent), is it considered a food? Tin is separated into stannic and stannous forms and combined with chloride to make stannous chloride, and then purified for use. At what stage does it become food? It is not reasonable that Congress would have intended to capture these types of products. FDA should clarify the definition and narrow the scope to include foods intended for consumption.

Define "import" to be consistent with Customs. The statute does not define "import" or "offered for import." U.S. Customs does not define "import" but does define "date of importation" as the date of arrival within the limits of a United States port "with intent then and there to unlade merchandise." FDA has determined that "offered for import" applies to all food that is brought across the U.S. borders including that intended for foreign trades zones, immediate re-export, and in-bond transport even if not intended for use or consumption within the U.S. FDA provides exclusion for food brought in personal baggage for consumption because FDA does not believe Congress intended such travelers to be "shippers" for the purposes of the Act. NFPA agrees that the suggested exclusion for personal baggage is appropriate. The Act repeatedly refers to "offered for import into the United States." Consequently, NFPA concludes that the intent of this provision of the Act was to identify articles of food intended for consumption by the citizens of the United States and that it would be appropriate, therefore, to exclude from the scope of these regulations food products that would be intended for immediate export and food products traveling under bond and food products not for consumption.

Clarify food contact material. FDA should clarify that only food contact material that is in contact with the food at the time of import would be considered under the scope of the regulation and that the "article" to be notified is the food product therein. The scope should not include dispensers, containers, or outside packaging that is not in direct contact with the food product.

Provide exemptions for research and development purposes and in-bond product. NFPA recommends FDA consider additional exemptions from prior notice requirements for products that are not destined for commercial or retail consumption within the United States. As noted above, products that ultimately fall under the jurisdiction of other national governments and are transported or held in-bond within the United States should be exempt from prior notice.

In addition, shipments that are sent directly to registered facilities within the U.S. for research and development purposes should, like personal baggage, also be exempt from prior notice. NFPA refers FDA to federal meat inspection regulations (9CFR, Part 327.16) and poultry inspection regulations (9CFR, Part 381.207), that provide a limited inspection exemption for meat and poultry products that are intended for personal consumption or laboratory analysis, but not for retail distribution. FSIS requires the shipment to contain a certifying statement describing the intended use. NFPA suggests that FDA take a similar approach relative to exemptions from prior notice requirements.

FDA has indicated that food products within exclusive jurisdiction of USDA are exempt from the requirements of this regulation. NFPA companies are confused about the scope of products under this exemption. Many food products are under dual jurisdiction. This exemption should be clarified to include any food products currently subject to FSIS mandatory inspection requirements.

The Proposal is Inconsistent with Trade Commitments

FDA indicates that "in implementing this proposed rule, FDA will comply fully with its international trade obligations" including those under the World Trade Organization (WTO) and NAFTA. NFPA respectfully disagrees with FDA; this proposal is inconsistent with the U.S. international obligations under the Agreement on Technical Barriers to Trade (TBT Agreement). The TBT Agreement recognizes national security and consumer health and safety as legitimate objectives, but NFPA asserts that this proposal is "more trade restrictive than necessary" to accomplish those safety and security objectives. Specifically, it is unnecessarily restrictive because many of the information elements require duplicate data already submitted to Customs, and FDA has failed to demonstrate a need for the detailed duplicative information required.

In addition, the time required for notice (noon the preceding day) exceeds the default minimum of 8 hours established by Congress and cannot reasonably be justified by FDA's assertion that

this time is necessary to "receive, review and appropriately respond" to the notification. If all ports of entry are not adequately staffed to manage the responsibilities under the Act, that issue should be addressed independently (see subsequent comments.)

Article 2.1 of the TBT Agreement requires WTO members to accord treatment "no less favorable than that accorded to like products of national origin and to like products originating in any other country." By establishing a reporting requirement of noon the day preceding entry, FDA has favored products shipped from more distant locations over those of our nearer neighbors such as Mexico and Canada. Those closer trading partners would shoulder a disproportionate burden of operational changes and disruption. In addition, the difference in time zones around the world makes compliance with the requirement unnecessarily confusing and complicated.

FDA has defined the party responsible for submitting the prior notice as an importer, purchaser or agent "who resides or maintains a place of business in the United States." Food companies indicate that in many cases this agent will be the U.S. Customs Broker. However, it is not uncommon for Canadian exporters to assume responsibility for shipments to the U.S., especially for shipments between establishments under the same ownership or when there is an established business relationship. Consequently, NFPA points out that requiring the submitter to reside in the U.S., may pose a particular operational and economic burden on Canadian shippers to identify and enter into a contract with a U.S. agent. Finally, FDA requests comments on allowing carriers to submit notice. The residence requirement would eliminate this option for non-U.S. resident carriers. FDA's reason for requiring U.S. residency is unclear and should be explained.

Recommendations – Honoring U.S. Trade Commitments

This proposal could satisfy U.S. international commitments if the requirement for notification was implemented in a less trade-restrictive manner that does not favor specific trading partners. To accommodate that, FDA should allow a shorter window for prior notice that allows products globally to make a submission within a specific number of hours prior to arrival at U.S. ports and should simplify the data submission to the elements mandated by the Act and those specifically necessary to identify and locate the product. NFPA also recommends FDA reconsider the need for an agent to be a U.S. resident.

The Proposal Fails to Take into Consideration the Effect on Commerce

The Bioterrorism Act recommends that FDA consider "the effect on commerce of such period of time, the locations of the various ports of entry into the United States, the various modes of transportation, the types of food imported into the United States and any other such

consideration." The Act directs FDA to specify a "period of time in advance of the time of the importation of the article of food..." which shall be no less than the minimum time necessary for FDA to "receive, review and appropriately respond to such notification." The Act establishes no minimum requirements, but sets an 8-hour "default" provision if FDA fails to promulgate regulations in a timely manner. FDA has established a notification deadline of noon the preceding day in order to "provide information to its field offices so they can allocate their inspectional resources on a daily basis and plan any necessary travel." FDA's proposal indicates that staff is not located at all of the 250 ports of entry. However, FDA's inspection staff, under FY 2003 appropriations, will be substantially increased to approximately 900, allowing all ports of entry to be appropriately staffed, consequently eliminating the need (except in extreme events) to "plan any necessary travel." In this regard, FDA has indicated that the information will be exchanged electronically and that "receive, review and respond" decisions can be flagged within seconds. Consequently, instructions to port officials to hold and inspect products should be able to be made within a minimum number of hours. Furthermore, establishing deadlines that appropriately reflect the realities of business operations and transportation would result in staggered receipt of prior notices by FDA and minimize the potential of overburdening either the technology and/or Agency officials.

NFPA agrees that the proposal "will have the most impact on those who import food by truck and rail over land borders." FDA calculates the potential loss for fresh produce and seafood but has failed to recognize loss to other product categories (certain processed products have limited shelf life) and costs related to storage and transportation. FDA believes "that the information required by prior notice will be, in most cases, sufficiently fixed by noon of the calendar day before arrival..." to enable prior notice "without slowing down the shipment." FDA bases this assumption on 64 packages of entry documents, even noting that this information was only available in 75 percent of the cases one day prior to import. FDA has concluded that allowing for one limited amendment and arrival updates will accommodate the "missing information" and fresh products.

Import Entry Documents. NFPA reviewed the 64 import packages on file in Dockets Management. FDA concluded that "in most cases, an invoice identifying the imported food was dated or contained a purchase date or data of sale that was at least one day before the arrival of the food or the receipt of the OASIS record." On the basis of an invoice, FDA extrapolated that "the information included in the entry documents of these records would be sufficient to submit the majority of the information require(d) for a prior notice." NFPA respectfully disagrees; the degree of detailed information on the import packages varied widely but our analysis does not validate FDA's assertion that the information required by prior notice is fixed when a purchase order is placed; only that the invoice predated the entry in 75 percent of the 64 cases.

FDA requested comments on the representative sample of import documents. NFPA provides the following observations: (1) Based on FDA's estimate of 20,000 prior notices; an "n" of 64 is not a representative sample; (2) Because business information has been blocked, it is not possible to assess the adequacy of carrier or other business information; (3) The sample does not include any frozen, refrigerated or other limited shelf-life processed foods which are a primary concern for NFPA members. All processed food in the sample was shelf-stable food products; (4) While invoices have been matched to entries, it is not possible to determine the accuracy of the information on the invoice or if entry times could have been predicted; and (5) FDA indicates that 12 of 64 invoices appear to have been created by the filer or broker, referred to as proforma invoices, some submitted as much as 2 days in advance. FDA has utilized that information to conclude the information would be available for prior notice. NFPA concludes "proforma" invoices may be for standing or recurring orders that are sent as products become available and thus are less likely to be accurately notified by the importer.

Operational Implications. FDA's proposal fails to take into account agreements with customers where orders are filled on a recurring basis based on production that may over or under fill purchase orders. In addition, it fails to take into account products that are shipped between establishments under the same ownership. Information about carriers, and Customs entry would rarely be found on a purchase order the day before entry, especially for truck cargo. Coordinating all the necessary data elements for a complete prior notification by noon the day before entry would entail several advance communications among carriers, shippers, importers and Customs brokers in addition to those existing in the current business environment.

Distribution and Holding. NFPA asserts that a "one-size fits all approach" will not work. Many food processors have establishments and/or customers on both sides of the border between Canada and the U.S. or Mexico and the U.S. Many are located only hours, or minutes from the border. Several shipments move daily across borders to satisfy "just in time" inventory requirements, sometimes responding to overnight requests. Establishments, particularly those dealing with perishable or code-dated products do not have "staging areas" or refrigerated warehouses for "holding" inventories. Often, the afternoon shift will produce food products to be immediately loaded onto trucks for shipment across the border. Lot numbers may be assigned just prior to loading. Lot sizes are limited to minimize the exposure in case a recall later becomes necessary. On some occasions, a product or specific production schedule may not be available the preceding day. For example, multiple products may be produced within one or two days on same production line to meet a standing order. Production schedules thus depend upon completion of the preceding production run. Under FDA's proposal the circumstance may arise where prior notice and, therefore, product lot codes must be filed before a product is even produced. The competing and conflicting time frames are production schedules, customer order deadline and prior notice deadline. The alternative is that products are held longer than might be required otherwise to meet the "noon the day before arrival" registration requirement.

The holding encroaches on shelf life, potentially introducing unnecessary safety and quality concerns. Many frozen and refrigerated products are code dated providing a very short window from production through the retail chain. U.S. retailers often require a minimum remaining shelf life upon delivery to allow ample marketing opportunity. Excessive border and inspection holds can also result in rejected products at delivery resulting in product loss. Holding costs money for fuel, refrigeration, personnel and marketing loss. Holding also adds new security concerns.

Amendment and Update. FDA has allowed one amendment related to product identity two hours in advance of entry. FDA allows for updating arrival information within a limited time window. How much of the information can be amended at that time and how many "updates" are permitted is not clear. FDA has grossly underestimated the number of amendments that will be necessary under the proposal. Several NFPA member companies have estimated that, for products arriving from Canada by truck, almost 100 percent of the submissions will require amendment, under the current submission timeframe. Many amendments will pertain to product identity including quantity, measure and lot identification. Many transportation details may not be available within FDA's time frame as well.

Arrival Times. Importers have little control of when a shipment actually arrives in the designated port of entry and less control over back-ups at the border. This will be affected by weather, traffic and conditions at border crossing. Under the current limited window, several updates may be required to reflect accurate arrival times. FDA has indicated that prior notice submissions must identify actual border crossing. Current practice along the U.S/Canada border allows truckers to select alternative border crossings depending upon traffic, subsequently facilitating transport and avoiding lengthy back-ups at the border. NFPA predicts that, unless FDA provides some flexibility about crossing points, back-ups at the border will be extreme. In fact, the Act is clear in stating: "Nothing in this section may be construed as a limitation on the port of entry for an article of food."

Specifically for products transported by sea, vessel arrival times vary widely depending upon weather conditions, scheduling and loading changes. Vessels can be held or detained at various ports enroute and importers are unlikely to be informed of these changes. Products from several importers are combined within one container. In these cases, linking prior notice information into the manifest to allow the carrier to provide a single "update" for a number of entries would minimize the use of resources and facilitate efficiency and accuracy. Rail cargo should be treated in a similar manner. The four-hour update window for sea vessels may be particularly problematic; these schedules change constantly. Establishing an exact time of arrival is not important because sea cargo is held in secure locations prior to unloading. FDA should exercise flexibility to accommodate unanticipated changes in vessel schedules.

Processors rely on air to meet last minute inventory needs required to keep production schedules on track. They also use air to ship small samples of products for research and development demands. Highly perishable products such as live shellfish are also shipped by air. Current practice allows cargo to be bumped at the last minute, frequently to accommodate scheduling changes or weight distribution requirements. Importers will not be informed and the cargo will then arrive on a subsequent flight by the same carrier or on a different airline under the same carrier.

Recommendations on Submissions, Amendments and Update

NFPA believes that, under the Act, FDA has sufficient flexibility to accommodate all of the above stated concerns. Reconsideration of these concerns is crucial in order to avoid gridlock at the border. NFPA makes the following specific suggestions:

1. **Set a definitive time frame based on transportation.** Provide a rolling window with a specific number of hours to provide notice in a manner that takes into account the specific needs of various modes of transportation. Notice for inbound sea cargo could be provided 24 hours in advance of entry into a U.S. port (this would also be consistent with Customs advance manifest requirement.) Four hours advance notice for cross-border truck and rail cargo would minimize border back-ups and accommodate operational realities to some extent. This window could be adjusted downward for low-risk recurring truck shipments close to the border, such as within 100 miles of the border. This alternative would require close cooperation with U.S. Customs in conjunction with established targeting programs (see following comments.) Air cargo notification should be provided at "wheels up," and eliminate the need for any amendments for cargo shipped by air.

2. **Increase flexibility for amendment.** Amendments should be permitted for all product identity fields, growers, customs and carrier data. Amendments should also be permitted for Customs entry and carrier information. Importers should be permitted to amend multiple factors in a single amendment submission. Under NFPA's suggested time frames, the need for amendments will be significantly reduced. Because importers have little control over unanticipated distribution factors, unlimited updates should be allowed within one-hour of entry. The notification requirements should be simplified so that amendments become the exception rather than the rule. An amendment dominant system increases costs for all stakeholders.

   Finally, FDA should retain some flexibility at the ports, to accommodate shipments from known shippers that have made a good faith attempt to meet the compliance responsibilities. Specifically, shipments from known shippers should not be held for minor infractions.

3. **Allow carriers to update information.** FDA should allow carriers to provide update information; this is particularly critical for air, rail and sea shipments when importers may not be informed of shipping delays or scheduling changes. The prior notice information should be linked to the manifest data so that a single "update" by the carrier can satisfy the prior notice requirement for a multitude of products to several importers simultaneously. This process would maximize the use of available resources and reduce the potential for error. Some importers have raised concerns to providing unlimited discretion to carriers to make substantive changes to submissions; but the need for carriers to make "updates' is essential to keep trade flowing.

4. **Simplify the submission.** FDA should eliminate all unnecessary data elements from the prior notification and strive to make the notification as simple as possible under the law. The form should provide for the simultaneous submission of several products with different codes or different common and usual names that may be arriving in the same shipment. FDA should not mandate specific quantity information but should allow for an estimate, a maximum, or a range. In addition, FDA should provide for flexibility to indicate package sizes, either by designating this information as voluntary or allowing for broad discretion in reporting (e.g. "cases of 24 cans"). NFPA asserts that it is completely unnecessary to specify precise quantities and exact measures of packages to establish the identity of the food. Similarly, lot production codes are of limited utility and should be eliminated as mandatory elements. By simplifying the submission requirement, the number of notifications including, amendments and updates will be greatly reduced, decreasing the burden on the importers and Agency.

5. **Allow flexibility in border crossing points.** The port of entry with customs code and anticipated arrival time is sufficient for FDA purposes. The port of entry code designates the city, state information. FDA should allow for alternative border crossings to prevent unnecessary backups at border points. The current trucking practice facilitates cross border traffic and maximizes the use of resources and personnel at border points.

6. **Allow split shipments notification in a single entry**. U.S. Customs has recently issued final rules to provide for "split entry" notifications. In this manner, FDA could accommodate several trucks from the same supplier simultaneously through the filing and receipt of a single notice, facilitating the entry process for all parties.

7. **Information about growers should not be required for processed food products.** Because the raw materials have been modified and transformed through processing, the identity of the growers becomes irrelevant. Consequently, FDA should clarify the reporting obligation for growers and, in no case should processed products from known shippers be held due to failure to complete these fields.

8. **Importer's liability needs clarification.** FDA should specifically clarify the importer's liability for notification violations that result from back-ups or failures at port of entry for all modes of transportation.

Summary of Submission Recommendations. Specifically, as discussed above, the submission should be simplified so that prior notice requirements include only the data elements mandated by the Act. FDA should clarify that growers are not required for processed food and that, for other products, only that grower information known at the time of notice is mandated. The notice should include the two parties responsible to FDA for notification and expenses. The notice should provide sufficient information to locate the product on entering the U.S. and provide flexibility on border crossings. Precise descriptions of product lots, quantities and measures are not necessary and should not be mandatory. (NFPA comments of March 3, 2003 discuss each data element in detail.)

Consistency, Not Duplication, with U.S. Customs is Critical

The Bioterrorism Act specifically mandates consultations between FDA and U.S. Customs Service. In comments submitted to FDA in August 2002, NFPA strongly urged FDA and Customs to work cooperatively towards seamless integration in order to avoid duplicative and redundant submission burdens on the trade. In fact, FDA indicates that substantive dialogue with Customs has transpired but still issued a proposal that precisely duplicates much of the existing data submission to Customs including the Customs entry, carrier and product code information. All of these elements are already provided to U.S. Customs that, as identified in FDA's proposal provides entry information to FDA via its Automated Broker Interface (ABI) of the Automated Commercial System (ACS), is downloaded into FDA's Operational Administrative System for Import Support (OASIS) from which FDA currently makes decisions to hold food entries. In addition, Customs is proceeding concurrently along separate paths towards mandating electronic submission of manifest data **prior** to entry. To illustrate this point, NFPA has attached a chart to demonstrate which elements are required in each system. This chart can help to identify where duplication should be eliminated.

FDA indicates that ACS could not be modified to accommodate the prior notice information before the statutory deadline of December 12, 2003 and that U.S. Customs will not be able to accommodate the data requirements for prior notice under the Automated Commercial Environment (ACE) system until 2005. Nevertheless, FDA has not provided information to explain why the current OASIS system with ABI interface could not be modified to accept the additional data elements mandated by the Act to provide a one-step release process for imported food shipments. It appears to NFPA that the new information will not be integrated with the current OASIS system or the Customs system. Rather an entirely new data collection system will be created, with duplicate elements of both systems.

FDA has correctly indicated that the proposed definition of country of origin may not be consistent with that of U.S. Customs. NFPA believes that consistency between FDA and Customs is important. For all products, the country of origin should be the country in which the food was produced or last processed. For example, FDA should amend the definition for country of origin to be the country in which the fish was harvested or last processed. Fish may originate from different flagship vessels, and become the combined catch from waters of several countries. From the standpoint of risk, whether food safety or security, it is the place of last processing that would be the most appropriate.

Finally, U.S. Customs rules do not allow information transmission on food products under tariff quotas until "Wheels ups" or they are inside U.S. waters. FDA requirements will conflict with those regulations.

Recommendations – Increase Consistency with Customs

1. **Importers should have a single reporting window to the U.S. government.** FDA should strengthen the dialogue with Customs particularly as Customs moves forward with new requirements for advance manifest submissions. FDA should not duplicate data elements already required by Customs and should review the data elements with the objective of simplifying notification requirements while still satisfying the mandates under the Act. In fact, FDA indicates, "Most of the information is already supplied by the filer to FDA through the ACS as part of the U.S. Customs entry process." Consequently, it is somewhat unclear why FDA cannot then advance receipt of that information through the existing systems to satisfy the requirements of the Act. FDA should work towards integrating those specific elements that are mandated through the Act into the existing OASIS system until such time the ACE can accommodate both the FDA additional information and Customs information requirements.

2. **Use consistent country of origin standards.** Definitions for country of origin should be consistent with those of U.S. Customs.

3. **Allow for the use of HTS Codes.** Consistent with coordinating information with U.S. Customs and minimizing duplication, FDA should consider allowing the use of U.S. Harmonized Tariff Schedule (HTS) codes to describe the goods entering the U.S. In this way the product descriptions would be consistent with existing Customs practice and familiar to international trade practice.

FDA Must Clarify Process and Procedures for Products Held

Under the Statute, if an article of food is being imported into the United States and notice in advance has not been provided, the article shall be held for proper notice or removed to secure storage. In § 1.278 FDA indicates that food shall be refused admission under section 801(m)(1) for failure to provide prior notice or inadequate notice is provided including untimely, inaccurate or incomplete. The economic consequences to provide secure storage and the potential of product loss can be devastating under this rule. NFPA supports holding high-risk products from entry but believes that the Statute provides FDA with some discretion for accommodating imports where a good faith effort has been demonstrated to provide notice but errors or omissions in data have been made. In this regard, consideration should be given to low-risk and known shippers (see comments below) in order to keep safe products moving appropriately through distribution channels.

Recommendations – Clarify Held Products

1. FDA should clarify and minimize the elements of the prior notice submission that are mandatory (as opposed to those that are voluntary) and will, therefore, result in refused entry.
2. FDA should establish criteria that allow shipments to proceed when insubstantial errors are made or when data is incomplete but insignificant.
3. FDA should issue prompt and clear guidance to field personnel and the industry that includes information about process and procedures when products are held and removed to secure storage. Specifically, FDA should identify the mechanism and timeframe to notify the submitter when product is held and released. FDA should clarify what information is required to affect a release.
4. FDA should identify field contacts and the locations of "secure" facilities that may be used for this purpose.
5. FDA should identify an appeal mechanism in the event food products are held without appropriate cause.
6. FDA should define "entry" and demonstrate some flexibility about timing of entry, especially taking into consideration border delays and factors outside the control of the importer.
7. FDA should not hold "low-risk" products for minor discrepancies in time or information.
8. FDA must examine and hold the goods in an environment conducive to keeping the food safe and secure and minimizing product deterioration and loss.

Recommendations - FDA Should Take Low-Risk Status into Account

In comments submitted in August, NFPA urged FDA to rely on the Customs existing security systems in order to keep commerce moving. NFPA noted that Customs has recently created Customs Trade Partnership Against Terrorism (CTPAT) to facilitate trade by participating

importers who have appropriate security systems in place. Many food companies have applied for CTPAT. FDA linkage into the CTPAT program would encourage food industry participation and assist both Agencies to achieve the ultimate statutory goal of improved food chain security. Customs already has a system in place to sort high risk cargo from low risk cargo (cargo selectivity system) and the ACS Entry Summary Selectivity System matches criteria against entry data to assess risk by importer, tariff numbers, country of origin, manufacturer, and value. In addition, Customs has linked CTPAT importers with carriers utilizing Free and Secure Trade (FAST) transport across the U.S. Canada border. As noted previously in these comments, other "known" shippers move identical products across borders on a daily basis. FDA has stated that it continues to consider opportunities to recognize low-risk importers and to cooperate with U.S. Customs and the food industry in this regard. However; the proposal makes no acknowledgement of comments received in this regard or indication that FDA is considering "low-risk" status.

FDA Has Underestimated Economic Impact

General Comments. NFPA believes that the economic impact of this proposal has been grossly underestimated. FDA has calculated the impact on importers but has failed to consider the economic and operational impact on all parties that must participate in the notification process including exporters, shippers and others. FDA calculations indicate that importers will file an average of 23.3 prior notices per year. In a survey of NFPA members, several responded that the proposed rule would require them to file thousands of notifications per year. All respondents indicated the number of imported articles had increased over the past year.

FDA has calculated potential product loss from holding at the border for only two product categories from Canada and Mexico: seafood and fresh produce. NFPA members produce processed products including dairy, frozen foods, juices and minimally processed products with limited shelf lives. Any foods that are code dated or carry "best before..." indicators on the label are sensitive to delays in distribution or unnecessary holding. NFPA members have significant experience with product losses caused by detainment at border points with these types of products.

FDA has based the economic impact analysis on four potential timing options but not options that take into account modes of transportation and/or allow for amendment within all the various options. Even then, FDA's estimated product loss is millions of dollars in all options. Finally, FDA has used data associated with foodbourne illnesses to calculate the benefits. NFPA agrees it is impossible to estimate the costs of an incident of intentional contamination or speculate how that cost could be mitigated by this regulation. Implementation of the proposed regulations alone are unlikely to result in identifying food that has been intentionally contaminated by foodbourne pathogens or other agents and, thus, mitigate those risks.

Specific Comments On The Economic Data.

Entry Lines: FDA used OASIS data to conclude that 4.7 million entry lines for food were imported into the United States in FY 2001. FDA fails to consider that the new regulations would mandate prior notice reporting for categories that may never have been filtered through OASIS under the previous system including the packaging components, and alcoholic beverages.

FDA estimates 4.7 million OASIS entries, averaging 2.6 lines each and notes that a prior notice will be required for each line. FDA then divides the entries by the lines to determine the number of prior notices. Under the proposal, one notice would be required for each article (line) and therefore 4.7 million must be multiplied by 2.6 "articles of food" to determine prior notice, yielding a total of 12.22 million prior notices. Obviously, allowing one notice per shipment could reduce this number.

FDA has estimated 20,000 prior notice submissions per day. In fact, if the regulation is adopted in its current form, the majority of these notices will be amended and then updated one or more times prior to entry. Therefore, FDA will be responding to many more notifications than anticipated.

Impact on Importers: FDA estimates that this regulation will affect 77,427 importers. FDA has failed to consider that this rule will also affect a large number of foreign suppliers and carriers who will have to adjust reporting procedures and scheduling to accommodate the time frame imposed by this new rule. NFPA has already identified the specific impact on Canadian exporters, who would be required to identify and reimburse a U.S. agent unfairly increasing costs of those exports.

In Table 24, FDA extrapolates (using the entry line assumption referenced above) that these importers will file an average of 23.3 prior notices annually. Under NFPA calculations (based on the current understanding of reporting requirements), FDA would receive over 12 million prior notices or well over 150 prior notices a year per importer. Clearly, many large importers will send several shipments across borders each day. Several NFPA members indicate they would file <u>thousands</u> of notices each year under the proposal. A single shipping container with a variety of products, will also, under the proposal, require numerous prior notices. According to FDA's calculations, an importer would receive less than two (2) articles per month on average; under the proposed "one" per article per notification, NFPA believes FDA has grossly underestimated the number of prior notices that would be filed.

Product Loss From Holding

FDA discusses five potential options, concluding only four would comply with the statutory mandates: (Option 2) Four hours or less for prior notice; (Option 3) Prior notice of 8 hours; (Option 4) Prior notice of noon the preceding day; or (Option 5) Prior notice noon the preceding day allowing for limited amendments 2 hours in advance. In Table 17, FDA has calculated the costs associated with each option and indicated that the least costly option would be the fourth proposed option, estimating a cost of $963 million, including $6 million in lost products. Under other options, the lost product is estimated as high as $307 million.

FDA incorrectly assumes that product losses would be limited to fresh produce and seafood arriving from Canada and Mexico. Product quality and safety for many product categories is adversely affected by excessive holding delays caused by notification submission and receipt or at border crossings. The U.S. imports $110 million in dairy products and over $1 billion in processed fruits and vegetables and juices, much of that is frozen and sensitive to deterioration if held for extensive periods. As previously stated, any product that is code-dated, or has limited shelf life may be adversely affected by holding periods.

Holding frozen or refrigerated goods in appropriately refrigerated trucks for up to 36 hours may not result in the same extent of loss from product deterioration as seafood and produce, but the costs for holding at the border will be significant and have not been factored into FDA's analysis. A trucking company will charge approximately $250 per hour to hold. If the refrigerated trucks are not kept running, products are compromised and must be destroyed. Running trucks at the border consumes fuel and contributes to environmental degradation. There are also real business costs associated with being unable to meet scheduled delivery times; this includes potential refusal at retail because the remaining shelf-life of a product does not satisfy market contracts. In addition, if the trucks contain any USDA product and are delayed, overtime inspection charges to satisfy FSIS requirements could be assessed at $60 per hour.

Food processing facilities strive to meet "just in time" inventory requirements. They generally do not have storage or staging facilities at the plants in which to hold products for any length of time after production. Under the production line scenario presented previously; product produced on an afternoon shift would require holding overnight to accommodate notification to FDA. Loading and holding in carriers (see costs identified previously) would not be a viable option; consequently processors would require in-house refrigerated storage introducing an additional step to the production process, thus incurring additional costs in personnel and equipment and more opportunity for introducing contamination or security breaches. Consequently, NFPA believes that economic costs under any of the options presented by FDA will be significantly greater than estimated.

FDA Must Consider More Options

FDA discussed five options to meet the statutory requirements. None of these options consider alternative notification mechanisms based on "modes of transportation and types of products," as clearly intended under the Act. In fact, NFPA suggests that there are numerous options that have not been considered by FDA.

Under option two, FDA concludes that if prior notice were required within four hours of entry; 20 percent of the shipments would require resubmission due to the fact that "40 to 100 percent of shipments are loaded onto vehicles less than four hours prior to entry." FDA concludes that the present value of costs associated with this scenario would be $1.6 billion.

Under option five; FDA concludes that if amendments and updates are permitted up to two hours in advance of entry; the number of resubmissions will be reduced from 40 percent to 5 percent, reducing the total costs of this options to only $963 million.

Using FDA's extrapolation, NFPA suggests that if option two (four hour prior notice) also allowed two-hour amendments and updates (as in Option 5) the number of resubmissions would also be reduced from 20 percent to 5 percent. This would, in turn, reduce the loss value in Mexican produce from$16.6 million to $2 million; the loss value for Canadian produce from $1.9 million to $241 thousand; the loss in Canadian seafood from $30.9 million to $3.9 million and Mexican seafood from $1.8 million to $235 thousand. Consequently, the Option 2 plus amendments would, under FDA calculations, equal those of option 5 (Table 16). Taking into account other costs identified by NFPA above that would be mitigated by this suggested new option further reduces the estimated costs in Table 16. Therefore, Option 2 plus amendments and updates would be the most cost effective.

Research: FDA estimates that the initial time to research prior notice requirements will be one hour. NFPA points out that this is a new and extremely complex and confusing new regulatory procedure. The consequences of error are potentially catastrophic; possibly resulting in held or lost product, down time of a production line, and subsequent loss of business sales and revenue. The initial research into the proposal already has numerous corporate executives scrambling to evaluate operational changes necessary to accommodate the rulemaking. This proposed regulation is not a simple paperwork exercise; it is a complex reporting procedure that will entail significant management oversight before it is delegated to agents or administrative staff. FDA has not taken into consideration time and expenses to train personnel and modify operation, to comply with this new requirement.

Form Completion: NFPA agrees that, once research is complete and a pattern is established, it would take approximately one hour to complete a full prior notice. This calculation, however,

does not take into consideration the time necessary to assemble and verify the detailed information on the proposed form. New communications with Customs, carriers and supplier must be initiated.

In addition, FDA has failed to appropriately take into consideration the time involved in amending and updating the information. Many importers from Canada and Mexico indicate that every prior notice will require amending and updating, under the proposal.

Many U.S. importers are likely to delegate prior notice filing responsibilities to Customs Brokers (agents). A preliminary estimate for a broker's time would be $50.00 to file and $20-25.00 for each amendment or update.

Recommendations To Reduce Economic Impact

Even under FDA's estimates, the economic burden of the proposal is significant. NFPA has identified a number of other costs that FDA has not taken into consideration. The Act provides FDA with a great deal of flexibility that enables the economic burden to be greatly reduced while still satisfying the mandates and the objective of the Act. NFPA recommends a rolling notification with a shorter window, elimination of duplicative and unnecessary data elements, allowing simultaneous notification for several articles, providing increased flexibility for updates and amendments and improved electronic interface with U.S. Customs to achieve that goal. In addition, facilitating notification and entry for low-risk shippers can significantly reduce resource burdens to the Agency and backlogs at border crossings. Providing user-friendly guidance to assist in compliance and limiting the amount of manual entry will reduce errors and related costs to benefit both the industry and regulators.

Recommendation: Transition Period Should Be Provided

NFPA has grave concerns regarding the ability of FDA personnel and technology to accommodate this significant new data dump by the effective date of December 12, 2003. Designating a single notification deadline (e.g. noon the preceding day) compounds that concern because we envision that the majority of the data will arrive between 10:00 a.m. and 12:00 noon imposing undue stress on technology. Considering the complexity of the proposal and it's global impact, NFPA believes that it is overly optimistic to expect a smooth transition on the implementation date in spite of substantive investment in outreach and education.

On December 2, 2002 U.S. Customs Service implemented regulations to require the electronic submission of manifest data 24 hours prior to entry into the U.S. by sea vessels. Customs recognized that the new regulations significantly modified the manner in which those vessels conducted business and the need to keep trade flowing. To accommodate that goal, Customs

provided for a 60-day informed compliance period during which time the Agency worked with the trade, providing additional guidance and information as necessary to facilitate a smooth transition. The 60-day window also provided an opportunity to assess the technology support and the information flow within the agency. No penalties were assessed during the 60-day period. Even now, U.S. Customs is reviewing the regulation because of compliance problems.

Considering the vast complexity of the FDA proposal and the excessive new technology and operational demands, NFPA strongly encourages FDA to integrate an "informed compliance" or other form of transition period into the implementation of this regulation. NFPA believes that the Statute provides FDA with enforcement flexibility after the December 12, 2003 effective date.

Summary

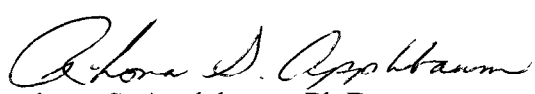
NFPA supports the important goals of the Bioterrorism Act and welcomes the opportunity to work with FDA to assure the safety and security of the U.S. food supply. NFPA is concerned about imposing unnecessary economic and operational burdens on the U.S. food industry, our foreign suppliers and U.S. consumers. NFPA believes that the objectives set forth in the Act can be satisfied in a more effective and cost efficient manner without misdirecting critical resources that could be better targeted to advancing food safety and security issues. Modifying this proposal according to the recommendations identified by NFPA will assist in that effort.

Specifically, NFPA urges FDA to simplify the notification to those elements necessary to meet the Congressional mandate, and to eliminate duplication of Customs requirements. The food industry asks for one submission window to the U.S. government. FDA must consider modes of transportation and the critical need to facilitate the huge volume of cross-border trade. Relying on the targeting programs of U.S. Customs to identify low-risk shippers and importers providing notification benefits and accelerating entry for those products will assist in achieving our collective security goals and the intent of the Act.

NFPA fully recognizes that the current environment is not "business as usual" and, consequently, the food industry is making every effort to tighten security throughout the food chain. Nevertheless, the economic consequences under the FDA proposal for the food industry, the Agency and ultimately food consumers are extreme. NFPA strongly urges FDA to consider recommendations offered here and to conclude that the important security objectives of the Bioterrorism Act can be achieved while simultaneously minimizing the adverse impact to commerce, both domestic and international.

Thank you for considering these comments.

Sincerely,



Rhona S. Applebaum, Ph.D.
Executive Vice President and Chief Science Officer

Comparison of FDA and U.S. Customs Prior Notice / Entry Requirements

	Information required for FDA 24 Hour Prior Notice	Information Required for U.S. Customs 24 hour Prior Notice	Customs Entry (Form 7501)
1	Submitter, including the name and firm information	Name of person signing and signature	Broker/Importer File No Declaration of Importer Signature
2	Entry type and U.S. Customs identification number, i.e., the ACS entry number;		Entry No. Entry Type Code
3	Product identity, including the FDA product code, the common or usual name, the trade name or brand name, and the lot codes and other identifiers	Full Commodity Description HTS Code [6 digits]	Description Line No. A-H.T.S.U.S. No. B-ADA CVD Case No.
4	Quantity of the food product	Number and Type of Packages Gross Weight of Cargo [Kilos]	Net Quantity in H.T.S.U.S. Units A-Gross Weight B-Manifest Qty.
5	Manufacturer		Manufacturer I.D. (ACE ID)
6	Grower, if known		
7	Originating country		Country of Origin
8	Shipper	Name of Shipper – Exporter Shipper – Exporter Full Name and Address w/ Pincode Shipping Bill Number	
9	Country from which the article of food was shipped	Port of Loading	Foreign Port of Lading Exporting Country
10	Anticipated arrival information: location, date, and time	Place of Delivery with State Code Place of Receipt Port of Discharge	US Port of Unlading Import Date Location of Goods/G.O. No.
11	U.S. Customs entry process information *(Port Code / Customs Date of Entry)*		Port Code Entry Date Entry Summary Date

			Export Date
12	Importer, owner, and consignee	Consignee – Full Name and Address with Zipcode	Consignee No. (ACE ID) Ultimate Consignee Name and Address Importer No. (ACE ID) Importer of Record Name and Address
13	Carrier	Name of Ocean Carrier Cargo Marks and Numbers Container Number[s] Seal Number[s] Vessel Name/Voy No. Booking Number assigned by Ocean Carrier Place of Issue of Cargo Declaration	Importing Carrier BL or AWB No. Mode of Transportation
			Bond No.
			Bond Type Code
			Missing Documents
			I.T. No. In Bond No in CATAIR
			I.T. Date
			Reference No. CF-4811 Reference No in CATAIR
			A-Entered Value B-CHGS C-Relationship (related party indicator in CATAIR)
			A-H. T.S.U.S. Rate B-ADA/CVD Rate C-LRC Rate D-Visa No. E-Other Fees
			Duty and IR Tax
			Duty
			Tax
			Other
			Total
			Extension Indicator